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Pharmacist's Manual

An Informational Outline of the Controlled Substances Act of 1970

Revised April 1986

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United States Department of Justice
Drug Enforcement Administration

An Informational Outline of the Controlled Substances Act of 1970

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This booklet has been prepared by the Office of Diversion Control as part of DEA's Diversion Control Program to assist pharmacists in their understanding of the Controlled Substances Act of 1970 and its implementing regulations as they pertain to pharmacy practice.

Revised April 1986

U.S. Department of Justice
Drug Enforcement Administration

Pharmacist's Manual

An Informational Outline of the Controlled Substances Act of 1970

Revised April 1986

Message from the Administrator

Dear Pharmacist:

The Drug Enforcement Administration is pleased to provide you with the fifth edition of the Pharmacist's Manual to assist in understanding the provisions of the Controlled Substances Act and the regulations. This booklet will answer questions that you may encounter in your practice concerning the dispensing of controlled substances and will give you guidance in complying with the regulations.

The fifth edition has been revised to include information on the provisions of the Controlled Substance Registrant Protection Act of 1984 and the Diversion Control Amendments.

The role of the pharmacist in the proper dispensing of controlled substances is critical both to the health of patients and to safeguard society against drug abuse and illicit diversion. The pharmacist's adherence to the law, together with voluntary service of its objectives, constitute a powerful resource for protecting the public health and safety.

Sincerely,

John C. Lawn

John C. Lawn
Administrator

READEX

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Preface

The Drug Enforcement Administration respects the professional integrity of pharmacists and recognizes that it can best serve the public interest by working together with pharmacists to develop acceptable and cooperative programs.

Over 60,000 community and hospital pharmacies are registered with the Drug Enforcement Administration to handle and dispense controlled substances. The vast majority of the pharmacists practicing in these pharmacies comply with the law and regulations in a responsible and law-abiding manner.

The Controlled Substances Act permits pharmacists to dispense controlled substances only pursuant to bona fide prescription orders issued in writing, or orally communicated to them by physicians authorized to prescribe controlled substances. For a prescription order to be effective, it must be issued for a legitimate medical purpose by a physician acting in the usual course of sound professional practice. While the responsibility for proper prescribing rests on the prescriber, a corresponding responsibility rests upon the pharmacist who dispenses the prescription medication. An order which is not written for a legitimate medical purpose is not considered to be a "*prescription*" within the meaning of the law and protects neither the physician who issued it nor the pharmacist who dispensed it.

Drug abuse is a serious problem. The diversion of legitimate drug products to the illicit market and the abuse of controlled substances is of great concern to the Drug Enforcement Administration. The importance of the pharmacist in the proper control of prescription drugs cannot be overemphasized. The pharmacist is in a pivotal position because it is the pharmacist who dispenses the prescription medication to the ultimate consumer. The pharmacist and the physician share the responsibility for controlling and monitoring the drug usage of patients. Consequently, patient health and proper drug usage depend upon concerned and interested professionals.

Pharmacists must be aware of the various methods and activities employed to divert controlled substances. The primary method is falsified prescription orders. Other methods for diverting controlled substances are: theft from a pharmacy, theft of prescription blanks, and willful and intentional diversion by pharmacists. The diversion of legitimately manufactured controlled substances is of great concern to DEA. State and local law enforcement agencies, as well as pharmaceutical industry representatives, cite prescription fraud as a substantial part of the problem. The DEA recognizes that attempts to obtain legitimately manufactured controlled substances by misrepresentation, such as forged prescription orders and stolen prescription blanks, are

significant problems confronting physicians, pharmacists, and local law enforcement agencies.

A number of programs have been established for alerting pharmacists of possible prescription forgeries. The programs generally provide a rapid communication system from pharmacy to pharmacy—to other health professionals—to DEA—to state/local law enforcement agencies. All these systems involve a telephone relay system to transmit timely information. We recommend that such systems be employed.

Several states have found that a multiple-copy prescription requirement provides a useful mechanism to control or curtail forged prescriptions and reduce overprescribing.

Close cooperation between the pharmacy profession and law enforcement will help ensure that legitimate controlled substances remain in legitimate channels.

Application of State Law and Federal Law

Nothing in this pamphlet shall be construed as authorizing or permitting any person to do any act which is not authorized or permitted under other Federal or State laws. In addition, none of the policy and information in this pamphlet may be construed as authorizing or permitting any person to do any act which is not authorized, or refuse to meet any requirements imposed under the regulations published in the most recent publication of Title 21, Chapter II, of the Code of Federal Regulations (21 CFR, Part 1300 to End). Printed copies of the complete regulations implementing the Controlled Substances Act of 1970 may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.* Proposed and finalized amendments to the regulations are published in the Federal Register.

In many cases State law is much more stringent than Federal law and must be complied with in addition to Federal law. This pamphlet is an informational outline of Federal law covering specific situations as outlined in the Federal Regulations.

*Editor's Note: Selected portions of the regulations promulgated under the Controlled Substances Act that are of most concern to pharmacists and physicians and students of pharmacy and medicine are presented in the United States Pharmacopeia as a service to the professions. They are provided at the suggestion of the Drug Enforcement Administration in accordance with its Diversion Control Program.

Drug Enforcement Administration

The Drug Enforcement Administration is the lead Federal law enforcement agency charged with the responsibility for combating controlled substance abuse. The Administration was established July 1, 1973 by Presidential Reorganization Plan No. 2 of 1973. It resulted from the merger of the Bureau of Narcotics and Dangerous Drugs, the Office for Drug Abuse Law Enforcement, the Office of National Narcotic Intelligence, those elements of the Bureau of Customs which had drug investigative responsibilities, and those functions of the Office of Science and Technology which were drug enforcement related. The Administration was established to control more effectively narcotic and dangerous drug abuse through enforcement and prevention. In carrying out its mission, the Administration cooperates with other Federal agencies, foreign as well as State and local governments, private industry, and other organizations.

Since 1914, the Congress has enacted more than 50 pieces of legislation relating to control and diversion of drugs. The Controlled Substances Act of 1970 became effective May 1, 1971. It collects and conforms most of these diverse laws into one piece of legislation. The law is designed to improve the administration and regulation of manufacturing, distribution, and the dispensing of controlled substances by providing a "closed" system for legitimate handlers of these drugs. Such a closed system should help reduce the widespread diversion of these drugs out of legitimate channels that find their way into the illicit market.

This informational outline has been prepared to acquaint pharmacists with requirements set up under the Controlled Substances Act of 1970, the 1984 Diversion Control Amendments, and the Controlled Substance Registrant Protection Act as they affect phamacy practice.

The drugs and drug products that come under the jurisdiction of the Controlled Substances Act are divided into five Schedules. There are some examples outlined in each schedule below. For a listing of controlled substances contact any office of the Drug Enforcement Administration. The addresses are listed in the back portion of this outline.

Schedules of Controlled Substances

The controlled substances that come under jurisdiction of the Controlled Substances Act are divided into five schedules.* Examples of controlled substances and their Schedules are as follows:

Schedule I Substances

The controlled substances in this schedule are those that have no accepted medical use in the United States and have a high abuse potential. Some examples are heroin, marijuana, LSD, peyote, mescaline, psilocybin, THC, MDA, ketobemidone, acetylmethadol, fenethyline, tilidine, methaqualone, dihydromorphine, and others.

Schedule II Substances

The controlled substances in this schedule have a high abuse potential with severe psychic or physical dependence liability. Schedule II controlled substances consist of certain narcotic, stimulant, and depressant drugs. Some examples of Schedule II controlled narcotic substances are: opium, morphine, codeine, hydromorphone (Dilaudid), methadone, pantopon, meperidine (Demerol), cocaine, oxycodone (Percodan), anileridine (Leritine), and oxymorphone (Numorphan). Also in Schedule II are amphetamine (Dexedrine) and methamphetamine (Desoxyn), phenmetrazine (Preludin), methylphenidate (Ritalin), amobarbital, pentobarbital, secobarbital, fentanyl (Sublimaze), etorphine hydrochloride, phenylacetone, and phencyclidine.

Schedule III Substances

The controlled substances in this schedule have an abuse potential less than those in Schedules I and II and include compounds containing limited quantities of certain narcotic drugs and nonnarcotic drugs such as: derivatives of barbituric acid except those that are listed in another schedule, glutethimide (Doriden), methyprylon (Noludar), nalorphine, benzphetamine, chlorphentermine, clortermine, phendimetrazine, and paregoric. Any suppository dosage form containing amobarbital, secobarbital, or pentobarbital is in this schedule.

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*Examples of trademark products appear in parentheses. Scheduling applies to all similar drug products of all other pharmaceutical manufacturers within each generic drug classification.

Schedule IV Substances

The controlled substances in this schedule have an abuse potential less than those listed in Schedule III and include such drugs as: barbital, phenobarbital, methylphenobarbital, chloral hydrate, ethchlorvynol (Placidyl), ethinamate (Valmid), meprobamate (Equanil, Miltown), paraldehyde, methohexital, fenfluramine, diethylpropion, phentermine, chlordiazepoxide (Librium), diazepam (Valium), oxazepam (Serax), clorazepate (Tranzene), flurazepam (Dalmane), clonazepam (Clonopin), prazepam (Verstran), lorazepam (Ativan), alprazolam (Xanax), halazepam (Paxipam), temazepam (Restoril), triazolam (Halcion), mebutamate, dextropropoxyphene (Darvon), and pentazocine (Talwin—NX).

Schedule V Substances

The controlled substances in this schedule have an abuse potential less than those listed in Schedule IV and consist of preparations containing limited quantities of certain narcotic drugs generally for antitussive and antidiarrheal purposes.

Retail Distribution Restrictions for Schedule V Substances

Schedule V controlled substances or any controlled substance listed in Schedule II, III, or IV which is not a prescription item under the Federal Food, Drug, and Cosmetic Act may be dispensed without a prescription order at retail provided that:

1) Such distribution is made only by a pharmacist and not by a nonpharmacist employee even if under the direct supervision of a pharmacist. However, after the pharmacist has fulfilled professional and legal responsibilities, the actual cash, credit transaction or delivery may be completed by a nonpharmacist.
2) Not more than 240 ml. (8 fluid ounces) or not more than 48 solid dosage units of any substance containing opium, nor more than 120 ml. (4 fluid ounces) or not more than 24 solid dosage units of any other controlled substance, may be distributed at retail to the same purchaser in any given 48-hour period without a valid prescription order.
3) The purchaser at retail is at least 18 years of age.
4) The pharmacist requires every purchaser at retail of a Schedule V controlled substance not known to the pharmacist to furnish

suitable identification (including proof of age where appropriate).

5) A Schedule V bound record book is maintained which contains the name and address of the purchaser, name and quantity of controlled substance purchased, date of each sale, and initials of the dispensing pharmacist. This record book shall be maintained for a period of two years from the date of the last transaction entered in such record book, and it shall be made available for inspection and copying by officers of the United States, authorized by the Attorney General.
6) Other Federal, state, or local law does not require a prescription order.

Symbols and Labeling

Each commercial container of a controlled substance is required to have on its label a symbol designating to which Schedule it belongs. The symbol for Schedule I through V controlled substances is as follows: Ⓒ or C-I; Ⓒ or C-II; Ⓒ or C-III; Ⓒ or C-IV; and Ⓒ or C-V. These symbols are not required on prescription containers dispensed by a pharmacist to a patient in the course of sound professional practice.

What the Prescription Medication Label Must Contain

The pharmacist dispensing a prescription order for a controlled substance must affix to the container a label showing the pharmacy name and address, the serial number and date of initial dispensing, the name of the patient, the name of the practitioner issuing the prescription order, and directions for use and cautionary statements, if any, contained in the prescription order as required by law.

The label of any drug listed as a "Controlled Substance" in Schedules II, III, or IV of the Controlled Substances Act shall, when dispensed to or for a patient, contain the following warning:

CAUTION: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.

Registration

Every pharmacy engaged in distributing or dispensing any controlled substance must register with the Drug Enforcement Administration.

The registration must be renewed every three years* and the certificate of registration must be maintained at the registered location and kept available for official inspections. If a person owns and operates more than one pharmacy, each place of business must be registered.

Every pharmacy will receive a reregistration application once every three years approximately 60 days before the expiration date of the registration. If such reregistration forms are not received within 45 days before the expiration date of the registration, the pharmacy must request the reregistration forms by writing to the Registration Unit of the Drug Enforcement Administration.

Public Interest Provision

The 1984 Diversion Control Amendments give the Attorney General authority to deny an application for registration if it is determined that the issuance of such registration would be inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.
(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
(5) Such other conduct which may threaten the public health and safety.

New Registrations

Pharmacies that seek to become registered for the first time must request a registration application for new registrants from the Drug Enforcement Administration, Registration Unit, P.O. Box 28083, Central Station, Washington, D.C. 20005, or from any DEA field office.

Any pharmacy engaged in co-op buying of controlled substances must register as a distributor with the Drug Enforcement Administration.

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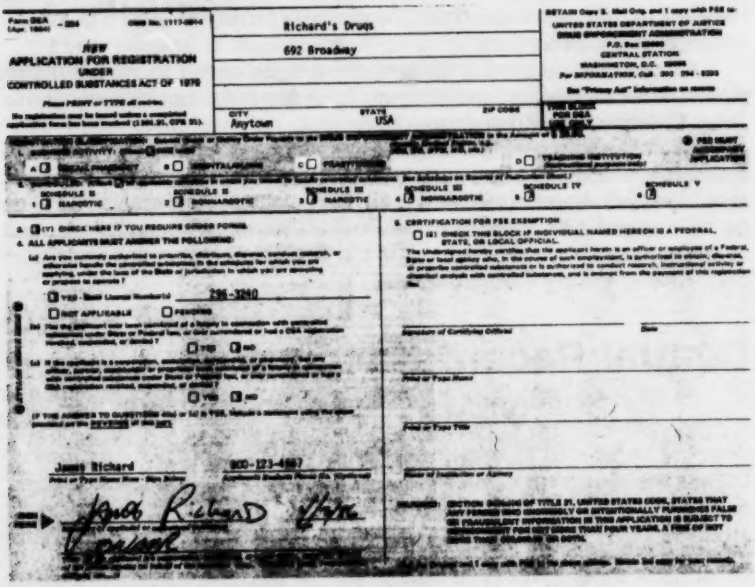
*Editor's Note: A three year registration certificate is authorized by provisions of the 1984 Diversion Control Amendments. The cost of the pharmacy for this three year registration certificate is $60.00.

In order to be registered as a distributor, a pharmacy must meet the security requirements as set forth for a distributor (wholesaler) and keep records required of a distributor.

An affidavit system for expediting pharmacy applications may be used to expedite obtaining a DEA registration number for either a new pharmacy or for the transfer of ownership of an existing pharmacy. Additional information may be obtained from any DEA office or section, 1301.38 of the DEA Regulations.



Richard's Drugs
692 Broadway
Anytown
USA
APPLICATION FOR REGISTRATION UNDER CONTROLLED SUBSTANCES ACT OF 1970
296-3240
James Richard
000-123-4567

Sample Form DEA 224 "Application for Registration"

Change of Business or Professional Address

The 1984 Diversion Control Amendments require that every registrant including pharmacies notify DEA of any change of business or professional address. Notification must be made, and the application approved prior to the anticipated move.

Records

Every pharmacy engaged in handling controlled substances must keep complete and accurate records of all receiving and dispensing transactions. All such records shall be maintained for a period of two years.

All inventories and records of controlled substances in Schedule II must be maintained separately from all other records of the registrant. All inventories and records of controlled substances in Schedules III, IV, and V must be maintained separately or must be in such form that they are readily retrievable from the ordinary professional and business records of the pharmacy.

All records pertaining to controlled substances must be made available for inspection and copying by duly authorized officials of the Drug Enforcement Administration.

When a registrant first engages in business and every two years thereafter, a complete and accurate inventory of all stocks of controlled substances on hand must be made. This inventory record shall be kept by the registrant for a period of two years. *Pharmacies are not required to submit a copy of the inventory to the Drug Enforcement Administration.* See Inventory Requirements.

Central Record Keeping

Central recordkeeping permits are no longer issued by the DEA. A registrant desiring to maintain required records at a location other than the registered location must notify the nearest DEA field office. Unless the registrant is informed by DEA that the permission to keep central records is denied, the registrant may maintain central records 14 days after notifying DEA. Section 1304.04 of the regulations describes central recordkeeping requirements.

Emergency Kits

The DEA has issued a statement of policy which provides individual state licensing and regulatory boards with general guidelines for the use and handling of controlled substances used in emergency kits for long term care facilities. Under these guidelines state agencies may promulgate specific rules. For a copy of the statement of policy contact your nearest DEA office.

Transfer of Prescription Information

Under this regulation, DEA will allow the transfer of prescription renewal information for Schedules III, IV, and V controlled substances between pharmacies if permissible under state law. The transfer of prescription renewal information is only allowable on a one-time basis.

Continuing Records to be Kept by a Pharmacy

Every pharmacy must maintain on a current basis a complete and accurate record of each controlled substance received.

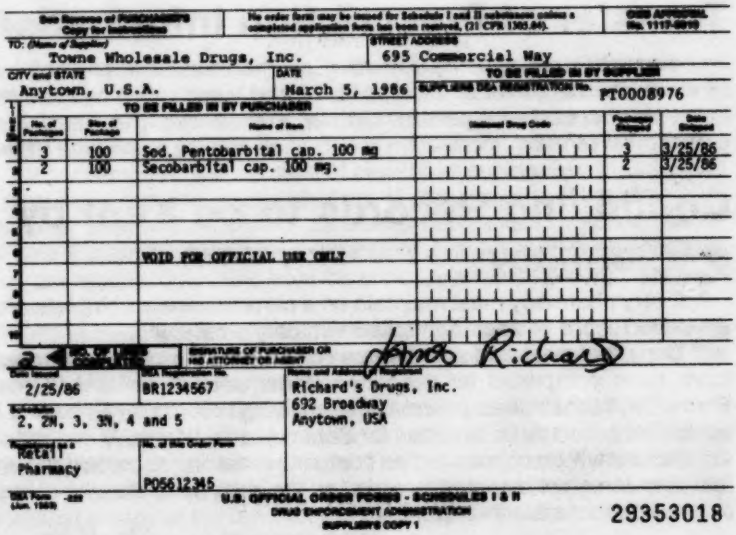
Copy 3 of executed order forms retained by the pharmacy which have been completed as described under section entitled "Order Forms" will constitute a pharmacy's receiving records for Schedule II controlled substances. Invoices for Schedules III, IV, and V controlled substances will be considered as complete receiving records *if the actual date of receipt is clearly recorded on the invoices by the pharmacist or other responsible individual.*

Order Forms

A triplicate order form is necessary for the transfer of controlled substances in Schedules I and II. Under the Controlled Substances Act, the use of the order forms will be for Schedules I and II drugs only. A registrant desiring DEA order forms can obtain them by requesting them on the initial application form or from the Drug Enforcement Administration, Registration Unit, P.O. Box 28083, Central Station, Washington, D.C. 20005.

Once a registrant has obtained DEA order forms a separate requisition form, DEA-222A, will be mailed to the registrant in order to request additional books. No charge is made for order forms.

When a registrant issues an order form for Schedule II controlled substances and after the items are received, the number of packages and the date such packages were received must be recorded on the retained copy. A space is provided for this on the DEA order form. The order form must be completed properly and bear no material alteration or erasure. A distributor is obligated to refuse the form if it is not properly completed, or if it bears material alteration or erasure. It may also be refused when it is not completed correctly.



TO: (Name of Supplier) Towne Wholesale Drugs, Inc.
STREET ADDRESS 695 Commercial Way
CITY and STATE Anytown, U.S.A.
DATE March 5, 1986
TO BE FILLED IN BY SUPPLIER
SUPPLIER'S DEA REGISTRATION No. PT0008976
TO BE FILLED IN BY PURCHASER

Item No.	No. of Packages	Size of Package	Name of Item	Quantity Shipped	Date Shipped
1	3	100	Sod. Pentobarbital cap. 100 mg	3	3/25/86
2	2	100	Secobarbital cap. 100 mg.	2	3/25/86
3					
4					
5					
6			VOID FOR OFFICIAL USE ONLY		
7					
8					
9					
10					

2 NO. OF LINES COMPLETED
SIGNATURE OF PURCHASER OR HIS ATTORNEY OR AGENT Richard's

Date Issued 2/25/86
DEA Registration No. BR1234567
Name and Address of Registrant: Richard's Drugs, Inc. 692 Broadway Anytown, USA
Schedules 2, 2N, 3, 3N, 4 and 5
Registered as a Retail Pharmacy
No. of this Order Form P05612345

DEA Form -222 (Rev. 1988)
U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II
DRUG ENFORCEMENT ADMINISTRATION
SUPPLIER'S COPY 1
29353018

Sample Form DEA 222 "Order Form"

DEA order form books consist of seven sets of order forms. Each pharmacy is allowed a maximum of six books at one time unless it can show that its needs exceed this limit. In such case, the pharmacy should contact the field office of DEA serving its area.

Power of Attorney

Any registrant (pharmacy) may authorize one or more individuals whether or not located at the registered location, to obtain and execute order forms by granting a power of attorney to each such individual. The power of attorney must be signed by the same person who signed the most recent application for registration or reregistration. It must contain the signature of the individual being authorized to obtain and execute order forms. Any power of attorney may be revoked at any time by the person who signed the power of attorney. It will be necessary to grant a new power of attorney upon the reregistration of a purchaser only if the application for reregistration was signed by a different person. The power of attorney should be filed with executed order forms. The power of attorney is not submitted to DEA. DEA does not provide power of attorney forms. See Title 21 of the Code of Federal Regulations, Section 1305.07 for a suggested form for the power of attorney and notice of revocation.

Lost or Stolen Order Forms

When unfilled order forms are lost, the pharmacy must execute a new form in triplicate. The pharmacy must also execute a statement containing the serial number and date of the lost form, stating that the drugs in the lost form were never received and attach a copy to Copy 3 of the lost form. Copy 3 of both the new and lost order form should be retained together. A copy of the statement should also be attached to Copies 1 and 2 of the newly executed order form.

When unused order forms are lost or stolen, the pharmacy must immediately, upon discovery of such theft or loss, report it to the Drug Enforcement Administration, Registration Unit, P.O. Box 28083, Central Station, Washington, D.C. 20005, stating the serial numbers of each form lost or stolen. If an entire book or books of order forms is lost or stolen, and the pharmacist is unable to state the serial numbers, the approximate date of issuance, in lieu of serial numbers, shall be reported.

If any unused order form reported stolen or lost is later recovered or found, the pharmacy shall immediately notify DEA at the above address.

Prescription Orders

Who May Issue

A prescription order for a controlled substance may be issued only by a physician, dentist, podiatrist, veterinarian or other registered practitioner who is:

1) Authorized to prescribe controlled substances by the jurisdiction in which licensed to practice;
2) Either registered under the Controlled Substances Act or exempted from registration (military and Public Health Service physicians).

See Section on Interns, Residents, and Foreign Physicians for additional information on issuance of a prescription order for a controlled substance.

Purpose of Issue

A prescription order for a controlled substance to be effective must be issued for a legitimate medical purpose by a physician acting in the usual course of sound professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing physician, but a corresponding liability rests with the phar-

macist who dispenses the prescription order. A request purporting to be a prescription order issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription order within the meaning and intent of Section 309 of the Controlled Substances Act. The person knowingly dispensing such a purported prescription order, as well as the person issuing it, will be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

Execution of Prescription Orders by Practitioners

All prescription orders for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, and the name, address, and registration number of the physician. A physician may sign a prescription order in the same manner as a legal document would be signed; for instance, J. H. Smith or John H. Smith. Where an oral order is not permitted (Schedule II), a prescription order must be written with ink or indelible pencil or typewritten and must be manually signed by the physician issuing such prescription order. The prescription order may be prepared by a secretary or agent for the signature of a physician, but the prescribing physician is responsible in case the prescription order does not conform in all essential respects to the law and regulations.

No prescription order for a controlled substance in Schedule II may be refilled. Such prescription orders must be kept in a separate file, or as outlined in the "filing of prescription orders for Controlled Substances" section of this manual. Prescription orders for controlled substances in Schedule III or IV may be issued either orally or in writing by a physician and may be refilled if so authorized. Such prescription orders may not be dispensed more than six months after the issue date or be refilled more than five times after the issue date. If a physician wishes a patient to continue on the medication, a new prescription order is required. Oral prescription orders must be promptly committed to writing and filed by the pharmacist.

A prescription order for a controlled substance listed in Schedule V may be refilled only as authorized by the prescribing physician on the prescription order. If no such authorization is given; the prescription order may not be refilled. For items which may be sold over-the-counter, however, the burden of determining the propriety of the dispensing is upon the pharmacist. See Retail Distribution Restrictions for Schedule V Substances.

Oral Authorization for a New Prescription

The authority for prescribing controlled substances is vested only in the physician and cannot be delegated to anyone else. However, nurses or staff members receiving calls from pharmacists regarding a new prescription may act as the physician's agent and transmit the physician's order.

Recording Refills

When a prescription order for any controlled substance in Schedule III or IV is refilled, the following must be entered on the back of that prescription order: the dispensing pharmacist's initials, the date the prescription order was refilled, and the amount of drug dispensed on such refills. If the pharmacist merely initials and dates the back of the prescription order, the pharmacist shall be deemed to have dispensed a refill for the full face amount of the prescription order.

Partial Dispensing of Schedule II Controlled Substances Prescription Orders

Partial dispensing of a Schedule II controlled substance* is permissible if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription order. The pharmacist may supply a portion of the quantity requested provided a notation is made of the quantity supplied on the face of the written prescription order (or written record of the emergency oral prescription). The remaining portion may be dispensed within 72 hours of the first partial dispensing; however, if the remaining portion is not or cannot be dispensed within the 72-hour period, the pharmacist shall so notify the authorizing practitioner. No further quantity may be supplied beyond the 72 hours except on a new prescription order.

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*The partial dispensing of a prescription order for Schedule II controlled substances beyond the 72-hour limitation is permissible for patients in long term care facilities. Specific procedures must be followed. Consult the nearest DEA office in your area for current information.

Partial Dispensing of Schedules III and IV Controlled Substances Prescription Orders

Partial dispensing of a Schedule III or IV controlled substance is permitted if the pharmacist dispensing or refilling the prescription order sets forth the quantity dispensed and initials the back of the prescription order. The partial dispensing may not exceed the total amount authorized in the prescription order. The dispensing of all refills must be within the six-month limit.

Filing of Prescription Orders for Controlled Substances

A prescription order for a controlled substance must be filed in one of the following three ways:

1) A pharmacy can maintain three separate files—a file for Schedule II drugs dispensed, a file for Schedules III, IV, and V drugs dispensed, and a file for prescription orders for all non-controlled drugs dispensed.
2) A pharmacy can maintain two files—a file for all Schedule II drugs dispensed and another file for all other drugs dispensed including those in Schedules III, IV, and V. If this method is used, the prescription orders in the file for Schedules III, IV, and V must be stamped with the letter "C" in red ink, not less than one inch high, in the lower right corner. This distinctive marking makes the records "readily retrievable" for inspection.
3) A pharmacy can maintain two files—one file for all controlled substances in all schedules and a second file for all prescription orders for non-controlled drugs dispensed. If this method is used, the prescription orders for controlled substances in Schedules III, IV, and V in the controlled substances prescription file must be stamped with the red letter "C" not less than one inch high in the lower right hand corner, as previously mentioned.

In states where the Uniform Controlled Substances Act (or other state law) requires all narcotic prescription records be kept together, DEA maintains that a positive conflict exists between Federal and state law and, under Section 708 of the Controlled Substances Act, Federal requirements prevail.

A prescription order written for office stock or "medical bag" use is not valid. Orders for Schedule II substances must be placed pursuant to an official order form.

Emergency Dispensing of Schedule II Controlled Substances

In the case of a bona fide emergency situation, as defined by the Secretary of Health and Human Services, a pharmacist may dispense a Schedule II controlled substance upon receiving oral authorization of a prescribing physician provided that:

1) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period. Prescribing or dispensing beyond the emergency period must be pursuant to a written prescription order.
2) The prescription order shall be immediately reduced to writing by the pharmacist and shall contain all information, except for the prescribing physician's signature.
3) If the prescribing physician is not known to the pharmacist, the pharmacist must make a reasonable effort to determine that the oral authorization came from a physician, by verifying the physician's telephone number with that listed in the directory and by making other good faith efforts to insure proper identity.
4) Within 72 hours after authorizing an emergency oral prescription order, the prescribing physician must cause a written prescription order for the emergency quantity prescribed to be delivered to the dispensing pharmacist. The prescription order shall have written on its face "Authorization for Emergency Dispensing." The written prescription order may be delivered in person or by mail, but if delivered by mail it must be postmarked within the 72 hour period. Upon receipt, the dispensing pharmacist shall attach this prescription order to the oral emergency prescription order which had earlier been reduced to writing. *The pharmacist shall notify the nearest office of DEA if the prescribing physician fails to deliver a written prescription order. Failure of the pharmacist to do so shall void the authority conferred by the subsection to dispense without a written prescription order of a prescribing physician.*

For the purpose of authorizing an oral prescription order of a controlled substance listed in Schedule II of the Controlled Substances Act, the term "emergency situation" means those situations in which the prescribing physician determines that:

1) Immediate administration of the controlled substance is necessary for the proper treatment of the intended ultimate user; and,

2) No appropriate alternative treatment is available, including administration of a drug which is not a controlled substance under Schedule II of the Act; and,
3) It is not reasonably possible for the prescribing physician to provide a written prescription order to be presented to the person dispensing the substance, prior to the dispensing.

An emergency means a situation where a quantity of a controlled substance may be dispensed by a pharmacist to a patient who does not have an alternative source for such substance reasonably available, and the pharmacist cannot obtain such substances through normal distribution channels within the time required to meet the immediate needs of the patient for such substance.

Computerization of Prescription Information

A pharmacy is permitted to use a data processing system as an alternative method for the storage and retrieval of prescription order refill information for controlled substances in Schedules III and IV.

The computerized system must provide immediate retrieval (via CRT display or hard-copy printout) of original prescription order information for those prescription orders which are currently authorized for refilling. The information which must be readily retrievable from this type of system must include, but is not limited to, data such as: the original prescription number; date of issuance of the prescription order by the physician; full name and address of the patient; the physician's name and DEA registration number; the name, strength, dosage form and quantity of the controlled substance prescribed; and the total number of refills authorized by the prescribing physician.

In addition, the system must provide immediate retrieval of the current refill history for Schedule III or IV controlled substance prescription orders that have been authorized for refill during the past six months and backup documentation to show that the refill information is correct. The backup documentation must be stored in a separate file at the pharmacy and be maintained for a two-year period from the dispensing date. See Specific Requirements, Section 1306.22 details for a computerized recordkeeping system.

Return of Controlled Substances to Supplier

Any pharmacy lawfully in possession of a controlled substance

listed in any schedule may return that substance (without being registered as a distributor) to the person from whom it was obtained or to the manufacturer of the substance. The controlled substance may be returned provided that a written record is maintained which indicates the date of the transaction; the name, form, and quantity of the substance; the name, address, and registration number, if any, of the person making the return; and the name, address, and registration number, if known, of the supplier or manufacturer. In case of returning a controlled substance listed in Schedule II, an order form shall be issued by the supplier to the pharmacy in the transfer of such substance. This section also applies to any other registrant who wishes to return controlled substances to a supplier.

Distribution by a Pharmacy

A pharmacy (as well as all physician registrants) registered to dispense a controlled substance may distribute (without being registered to distribute) a quantity of such substances to a physician for the purpose of dispensing by that physician provided that the following conditions are met:

1) The pharmacy or physician to which the controlled substance is being distributed is registered under the Act to dispense that controlled substance.
2) The distribution is recorded as being distributed by the pharmacy and the receiving pharmacy or physician records the substance being received. The pharmacy distributing a controlled substance must record the name of the substance, the dosage form, the quantity and the name, address, and DEA registration number of the pharmacy or physician to whom it is distributed on an official order form.
3) If the substance is listed in Schedule I or II, the transfer must be made on an official order form.
4) The total number of dosage units of controlled substances distributed by a pharmacy may not exceed 5 percent of all controlled substances dispensed by the pharmacy during the 12-month period in which the pharmacy is registered. If at any time it does exceed 5 percent, the pharmacy is required to register as a distributor as well as a pharmacy.

Controlled Substance Security

The Drug Enforcement Administration requires pharmacies to keep Schedules II, III, IV, and V controlled substances in a locked cabinet

or dispersed through the non-controlled stock to deter theft. An electronic alarm system is recommended.

Controlled Substance Destructions

A pharmacy to dispose of any excess or undesired stocks of controlled substances is required to contact the nearest state or DEA office for disposal instructions and to request the necessary form (DEA-41).

The DEA office will advise the registrant of the procedures to be followed which will consist of one of the four courses of action listed below.

1) The pharmacy will be advised that the drugs may be destroyed by two responsible parties employed or acting on behalf of the registrant. This course of action will be used when there are factors which preclude an on-site destruction witnessed by DEA personnel, such as the firm's history of compliance and the abuse potential of the drugs involved.
2) The pharmacy will be advised to forward the excess of undesired stocks of controlled substances to the appropriate state agency for destruction. In lieu of actual surrender to the state agency, destructions witnessed by state personnel are acceptable.
3) The pharmacy will be advised to hold the substances until DEA can witness the destruction of the substances. DEA personnel will date and sign the reports or forms after witnessing the destruction.
4) The pharmacy will be advised to forward the substances to the DEA Field Office which serves the area in which the registrant is located. Upon receipt of the substances, the DEA Field Office will verify the actual substances submitted. If errors are found, a corrected form must be prepared and the registrant duly notified. The original form will be returned to the registrant.

Regardless of the destruction procedures used, three copies of DEA Form-41 are required. The procedures established for destruction shall not be construed as affecting or altering in any way the disposal of controlled substances through procedures in laws and regulations adopted by any state.

Controlled Substance Theft

A pharmacy involved in theft or significant loss of controlled substances must upon discovery notify the nearest DEA office in addi-

tion to reporting such theft to the local police. The pharmacy must make a report regarding the theft or loss by completing DEA Form-106. The Code of Federal Regulations implements CSA requirements that notification be made.

Such report shall contain the following information:

1) Name and address of firm.
2) DEA Registration Number.
3) Date of theft.
4) Local police department notified.
5) Type of theft (night break-in, armed robbery, etc.).
6) Listing of symbols or cost code used by pharmacy in marking containers (if any).
7) Listing of controlled substances missing through theft or significant loss.

The pharmacy is required to prepare the report in triplicate and retain the third copy for its records and forward the original and duplicate copies to the appropriate DEA office.

Controlled Substance Registrant Protection Act of 1984

On May 31, 1984, Congress approved the Controlled Substance Registrant Protection Act of 1984. Robberies, burglaries and assaults perpetrated on pharmacists and other registrants are a serious problem in the United States. These crimes result in property loss and sometimes serious injury to professionals and innocent bystanders. The proceeds from thefts and robberies serve to fuel the drug abuse problem.

The Controlled Substance Registrant Protection Act of 1984 mandates Federal Investigation if any of the following conditions are met:

1) Replacement cost of the controlled substances taken is $500 or more.
2) A registrant or other person is killed or suffers "significant" bodily injury during the commission of the controlled substance robbery or theft.
3) Interstate or foreign commerce is involved in planning or executing the crime.

The penalties for violating the Act's provisions are as follows:

1) Conviction for commission of burglary or robbery can result in a maximum $25,000 fine and/or 20 years imprisonment.
2) Conviction for use of a dangerous weapon in the commission of the crime can result in a maximum $35,000 fine and/or 25 years imprisonment.

3) If death results from the crime, the convicted person can receive a maximum $50,000 fine and/or life imprisonment.

It is hoped that the Controlled Substance Registrant Protection Act of 1984 will have a significant deterrent effect in preventing these criminal activities.

Distribution Upon Discontinuance or Transfer of Business

A registrant discontinuing controlled substances business, and who does not transfer such business activities to another person shall return the certificate of registration and any unexecuted order forms to the Registration Branch, Drug Enforcement Administration, Department of Justice, Post Office Box 28083, Washington, D.C. 20005. If a registrant discontinues controlled substances business and transfers such business activity to another person, the certificate of registration and any unexecuted order forms are also required to be returned. It is recommended unused order forms be marked "VOID" by the registrant prior to being sent to DEA. The new owner requires a new registration.

Any controlled substances in the registrant's possession may be disposed of in accordance with instructions under the section: Drug Destructions.

A registrant discontinuing controlled substances business altogether, or transferring it to another person, shall submit in person or by registered mail the following information to the nearest DEA office at least 14 days before the date of the proposed transfer:

1) The name, address, registration number of the pharmacy discontinuing business;
2) The name, address, registration number of the person acquiring the pharmacy;
3) Whether the business activities will be continued at the location registered by the person discontinuing business or moved to another location. If the latter, the address of the new location shall be stated;
4) The date on which the transfer of controlled substances will occur.

On the day of transfer of the controlled substances, a complete inventory of all controlled substances being transferred shall be taken. This inventory shall serve as the final inventory of the registrant transferor and the initial inventory for the registrant transferee, and a copy of the inventory shall be included in the records of each person.

It is not necessary to file a copy of the inventory with the DEA. Transfers of any substances listed in Schedule II shall require the use of order forms.The order forms of the transferee are to be used for thetransfer.

On the date of transfer of the controlled substances, all records required to be kept by the registrant transferor with reference to the controlled substances being transferred shall be transferred to the registrant transferee. Responsibility for the accuracy of records prior to the date of transfer remains with the transferor, but responsibility for custody and maintenance shall be upon the transferee.

Editor's Note: The 1984 Diversion Control Amendments require that registrants must notify DEA of any change of professional or business address. Notification to DEA must be made prior to the anticipated move.

Inventory Requirements

The Controlled Substances Act (P.L. 91-513) requires each registrant to make a complete and accurate record every two years of all stocks of controlled substances on hand.

Initial Inventory

A registrant is required to take an initial inventory on the date when controlled substances activities are first engaged. In the event that no controlled substances are on hand at the initial inventory a zero inventory is to be recorded.

The inventory record must:

1) List the name, address, and DEA registration number of the registrant.
2) Indicate the date and the time the inventory is taken, i.e., opening or close of business.
3) Be signed by the person or persons responsible for taking the inventory.
4) Be maintained at the location appearing on the registration certificate for at least two years.
5) Keep records of Schedule II drugs separate from all other controlled substances.

Biennial Inventory

Every two years following the date of the registrant's initial inventory, a new inventory must be taken. The information required on the biennial inventory is the same as that for the initial inventory. The biennial inventory date may be changed by the registrant to fit the regular general physical inventory date, if any, so long as the date is not more than six (6) months from the biennial date that would otherwise apply. The actual taking of the inventory should not vary more than four (4) days from the biennial inventory date. A registrant desiring to change the biennial inventory date must notify in advance the nearest DEA office of the date on which the inventory is to be taken.

When taking the inventory of Schedule II controlled substances, an exact count or measure must be made. When taking the inventory of Schedules III, IV, and V controlled substances, an estimated count may be made. If the container holds more than 1,000 dosage units, an exact count must be made if the container has been opened.

Newly Controlled Substances—occasionally a drug that has not been previously controlled will be placed in one of the drug schedules or a controlled substance will be moved into a higher or lower schedule. In either of these cases, the drug must be inventoried as of the effective date of transfer, and this inventory added to the biennial inventory. Also see the section on Records.

Excessive Purchases of Controlled Substances

Pharmaceutical manufacturers and drug distributors are required to design and operate a system to disclose suspicious orders of controlled substances. The DEA office in the area of the manufacturer or wholesaler must be notified of such suspicious orders. Suspicious orders for controlled substances include orders of unusual size (excessive purchases), orders deviating substantially from a normal pattern, and orders of unusual frequency. To assist the DEA in monitoring controlled substances purchases, a computer system is utilized for tracking selective controlled substances purchases including those from multiple sources of supply.

Interns, Residents, and Foreign Physicians

Any physician who is an intern, resident, foreign physician, or physician on the staff of a Veterans Administration facility (exempted from registration), may dispense, administer, and prescribe controlled substances under the registration of the hospital or other institution in which the physician is employed provided that:

1) The dispensing, administering, or prescribing is in the usual course of sound professional practice;
2) The physician is authorized or permitted to do so by the state where practicing;
3) The hospital or institution has verified that the physician is permitted to dispense, administer, or prescribe controlled substances within the state;
4) The physician acts only within the scope of employment in the hospital or institution;
5) The hospital or other institution authorizes the physician to dispense or prescribe under its registration and assigns a specific internal code number for each physician so authorized. An example of a specific internal code number is as follows:

Hospital DEA Registration Number	*AB1234567—012	Physician's Hospital Code Number

6) A current list of internal codes and the corresponding individual practitioners is kept by the hospital or other institution and is made available at all times to other registrants and law enforcement agencies upon request for the purpose of verifying the authority of the prescribing individual practitioner.

Pharmacists should contact the hospital or other institution for verification if they have any doubts in dispensing such prescription orders.

Military and Other Personnel

Any official of the U.S. Army, Navy, Marine Corps, Air Force, Coast Guard, Public Health Service, or Bureau of Prisons who is authorized to prescribe, dispense, or administer, but not to procure or purchase, controlled substances in the course of official duties is not required to be registered with DEA.

*Editor's Note: DEA registration numbers for physicians generally start with the letter "A". "New" registrants will be assigned the letter "B" as a first digit after June 1, 1985. There will be no change in the registration number of persons who already have the letter "A" as a first digit.

Narcotic Treatment Programs (Methadone Clinics)

The Narcotic Addict Treatment Act of 1974 (P.L. 93-281) was signed into law on May 14, 1974. The Act designates which government agencies have control over narcotic treatment programs and the basic requirements of each. The Act further defines the terms "maintenance" and "detoxification" and explains who has to register to treat patients for drug dependence.

In the October 25, 1974 issue of the Federal Register, DEA regulations regarding narcotic treatment programs were published in final form. They became effective as part of Title 21, Code of Federal Regulations, Chapter 1300, on November 15, 1974. These regulations state in detail DEA's requirements regarding narcotic treatment programs.

Record keeping and security requirements are very similar to those required of a pharmaceutical distributor or manufacturer.

Order forms are required for all Schedule II narcotic transactions between the supplier and the narcotic treatment programs. This includes the transfer of Schedule II narcotics from the manufacturer or distributor to the dispensing location.

At the present time, a narcotic treatment program can obtain six (6) books of order forms (DEA Form 222) from DEA at any one time.

Narcotic treatment programs registered with DEA can handle only the narcotics that they apply for on their DEA Form 363 (registration application) and are approved for use for maintenance in detoxification. Controlled substances for treatment of conditions other than narcotic addiction cannot be administered, dispensed or stored on the premises of a narcotic treatment program at any time, unless the program possesses a practitioner registration at the location of the narcotic treatment program.

Below is a list of definitions regarding narcotic treatment programs:

Maintenance Treatment

The dispensing, for a period in excess of 180 days, of a narcotic drug in the treatment of an individual for dependence upon heroin or other morphine-like drugs.

Detoxification Treatment

The dispensing, for a period not in excess of 180 days, of a narcotic drug in decreasing doses to an individual in order to alleviate adverse physiological or psychological effects incident to withdrawal

from the continuous or sustained use of a narcotic drug, as a method of bringing the individual to a narcotic drug-free state within such period.

Compounder

An entity engaging in maintenance treatment or detoxification treatment which also changes the dosage form of a narcotic drug for use in maintenance treatment or detoxification treatment at other locations.

There are six (6) registration categories (business activities) of Narcotic Treatment Programs:

1) Maintenance Program Only
2) Detoxification Program Only
3) Maintenance and Detoxification Program
4) Compounder with a Maintenance Program
5) Compounder with a Detoxification Program
6) Compounder with both a Maintenance and Detoxification Program

Every program must register under the category which applies to its business activity.

A program may register for detoxification and/or maintenance or compounder with detoxification and/or maintenance. The program must register as a compounder if they compound narcotics on the premises for use at a program on-site and off-site. If compounding or distribution for other programs occurs at a location where no program exists, then the compounding location must register with DEA as a manufacturer and/or distributor.

Problems have arisen regarding narcotic prescription orders (primarily in methadone). According to DEA regulations, a physician may prescribe methadone or any other narcotic for a patient for analgesic purposes only. A patient who is to be or is being maintained or detoxified cannot receive a narcotic prescription order for this purpose. The patient must receive the necessary narcotics at a registered narcotic treatment program. In this case, the narcotic can be dispensed or administered to the patient, but not prescribed.

Furthermore, the regulations state that only four specific individuals employed by the narcotic treatment program can dispense or administer narcotics to the patients: (1) the licensed physician, (2) a registered nurse under the direction of the licensed physician, (3) a licensed practical nurse under the direction of the licensed physician, or (4) a pharmacist under the direction of the licensed physician. This regulation prohibits the receptionist or counselor or another untrained individual (in some cases even a patient) from administering narcotics to the patient.

Sections 1306.07(b) and (c) of Title 21, CFR have also raised several questions regarding Narcotic Treatment Programs:

A physician who is not part of a narcotic treatment program may administer narcotic drugs to an addicted individual on a daily basis for not more than a three (3) day period to relieve that individual's acute withdrawal symptoms while the physician makes arrangements to enroll the individual in a narcotic treatment program. This treatment cannot last more than three (3) days and may not be renewed or extended.

A hospital that has no program on the premises or a physician who is not part of a treatment program may administer narcotics to a drug dependent individual for either detoxification or maintenance purposes if the individual is being treated for a condition other than the addiction. It is assumed that the physician or hospital staff will not take advantage of this situation and detoxify or maintain a drug dependent person who has sustained a very minor injury or illness which will not prevent the person from going to a registered program. Also, a physician is allowed to exercise sound medical judgment and to dispense or administer narcotics to an individual for extended periods for the purpose of relieving intractable pain for which no other relief or cure is known. An example of this would be terminal cancer patients or patients with painful chronic disorders.

Questions regarding any part of the Narcotic Addict Treatment Act of 1974 or any part of the regulations pertaining to the Act, should be directed to the nearest office of the Drug Enforcement Administration or the Food and Drug Administration.

Postal Services Mailing Requirements for Controlled Substances

The following are the mailing rules as set forth in the U.S. Postal Service Domestic Mail Manual, 11-1-81, Issue 7.

124.364 Controlled Substances (18 U.S.C. 1716)

.364 Controlled Substances

a. A controlled substance is any narcotic, hallucinogenic, stimulant or depressant drug in Schedules I through V of the Controlled Substances Act (Public Law 91-513), 21 U.S.C. 801, et seq., and the regulations thereunder, 21 CFR 1300, et seq.

b. Narcotic drugs, as defined in the Controlled Substances Act, include opium, cocaine and opiates (synthetic narcotics) and the derivatives thereof.

c. Controlled substances are, by reason of their addictive nature or capacity for abuse, hereby declared to be Articles, compositions, or materials which may kill or injure another within the intent and meaning of 18 U.S.C. 1716.

d. Except under the conditions specified in 124.365, controlled substances are nonmailable matter and must not be conveyed in the mails or delivered from any post, branch or station thereof nor by any letter carrier.

.365 Mailing Requirements

a. Authorized Mailings.

Controlled substances may be transmitted in the mails between persons registered with the Drug Enforcement Administration or between persons who are exempted from registration such as military, law enforcement, and civil defense personnel in the performance of their official duties. Prescription medicines containing nonnarcotic controlled substances may be mailed from a registered practitioner or dispenser to an ultimate user. Prescription medicines containing narcotic drugs may be mailed only by Veterans Administration medical facilities to certain veterans. Parcels containing controlled substances must be prepared and packaged for mailing in accordance with the requirements of 124.365b.

b. Preparation and Packing

1) The inner container or any parcel containing controlled substances must be marked and sealed in accordance with the applicable provisions of the Controlled Substances Act, 21 U.S.C. 801, and the regulations promulgated thereunder, 21 CFR 1300, et seq.
2) The inner container of prescription medicines containing controlled substances must, in addition to the marketing and sealing requirements set forth in 124.365b, be labeled to show the name and address of the practitioner, or the name and address of the pharmacy or other person dispensing the prescription (if other than the practitioner), and the prescription number.
3) Every parcel containing controlled substances must be placed in a plain outer container or securely over-wrapped in plain paper.
4) No markings of any kind which would indicate the nature of the contents shall be placed on the outside wrapper or container of any parcel containing controlled subtances.

c. Exempt Shipments.

Small quantities of unknown matter suspected of containing controlled substances may be sent by regular mail without regard to the other provisions of 124.364 only when addressed to a Federal, State, or local law enforcement agency for law enforcement purposes. Such mailings must comply with 124.365b (3) and (4).

.366 Violations.

Violations of this section must be referred to the Inspection Service.

The Pharmacist's Corresponding Responsibility for Controlled Substance Prescription Orders*

Title 21, Code of Federal Regulations, *Section 1306.04* provides, in pertinent part, that:

"A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, ***but a corresponding responsibility rests with the pharmacist who fills the prescription.*** *An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of Section 309 of the Act (21 USC 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances." (Emphasis supplied)*

A pharmacist is required to exercise sound professional judgment with respect to the legitimacy of prescription orders dispensed. The law does not require a pharmacist to dispense a prescription order of doubtful origin. To the contrary, the pharmacist who deliberately turns the other way when there is every reason to believe that the purported prescription order had not been issued for a legitimate medical purpose may be prosecuted, along with the issuing physician, for knowingly and intentionally distributing controlled substances, a felony offense which may result in the loss of one's business or profession. See **United States v. Kershman**, 555 F.2d 198 (U.S. Ct. of App., Eighth Circuit, 1977).

The following is a list of indicia which may indicate that a purported prescription order was not issued for a legitimate medical purpose in the course of the physician's professional practice. This list is admittedly not exhaustive. Pharmacists are encouraged to suggest additional techniques by which they have been able to detect illegal and fraudulent prescription orders.

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- Does the purported prescription order contain an indication other than one found in the package insert?

- Does the prescriber write significantly larger numbers of prescription orders (or in larger quantities) compared to other practitioners in your area?

- Does the prescriber write for antagonisitic drugs, such as depressants and stimulants, at the same time? Drug abusers often request prescription orders for "ups and downs" at the same time.

- Do patients appear to be returning too frequently? In numerous cases drug abusers have been found to be receiving prescription orders, which ought to have lasted for a month in legitimate use, on a bi-weekly, weekly, or even a daily basis.

- Do patients appear presenting prescription orders written in the names of other people?

- Do a number of people appear simultaneously, or within a short time, all bearing similar prescription orders from the same practitioner?

- Are numerous "strangers," people who are not regular patrons or residents of your community, suddenly showing up with prescription orders from the same physician? Typically, you will find that these individuals are in the 18 to 25 year age group, although drug abuse does not necessarily end with the achievement of chronological maturity.

- Are your purchases of controlled substances rising dramatically? If so, it is time to look at your prescription counter policies. Drug abusers may have found a "vendor" who dispenses prescription orders mechanically, without using professional judgment.

Having found one or more of the above-described symptoms, what is the pharmacist expected to do? Like most people, pharmacists are reluctant to "get involved." Unlike most people, though, the pharmacist really has no choice—the pharmacist is involved, with responsibilities as a professional, a licentiate, and a DEA registrant. In the case of one or two prescription orders which appear to be irregular, the best remedy may well be a call to the concerned physician. Often, a friendly bit of advice from a fellow professional may be all that is needed to nip a prescribing problem in the bud.

However, where there appears to be a pattern of prescription order abuses, a word to the wise and the mere refusal to dispense certain prescription orders may not be enough. Abusers will simply go elsewhere, possibly to another pharmacist with whom the prescriber has an understanding. In such cases, the pharmacist should waste no time in contacting the State Board of Pharmacy or the local office of the Drug Enforcement Administration. Both DEA and State authorities consider retail-level diversion as priority problems. Your information will be handled confidentially and will receive prompt attention. DEA cannot, however, get to the source of the diversion without your cooperation.

Dealing with Forged Prescription Orders*

The only way a passer of forged prescription orders can obtain controlled substances is by presenting a prescription order—written or oral—to a pharmacist. Thus, it is important that the dispensing pharmacist maintain a constant vigilance against forged prescription orders.

A prescription order represents any request by an authorized prescriber for the dispensing, or the administration, to a particular patient—of a particular quantity of a particular drug, in a particular dosage form and strength, for use according to particular directions, to treat a particular condition of health, at a particular time.

The problem of the diversion of legitimately manufactured controlled substances is a source of constant concern to the Drug Enforcement Administration. Repeatedly, state and local law enforcement agencies, as well as pharmaceutical industry representatives, cite prescription fraud as a substantial part of this problem.

The DEA recognizes that attempts to obtain legitimately manufactured controlled substances by misrepresentation—i.e., forged prescriptions and stolen prescription blanks—are significant problems confronting pharmacists and local law enforcement agencies. With the passage of the Comprehensive Drug Abuse Prevention and Control Act of 1970, more stringent controls were placed on the dispensing of controlled substances by pharmacists. There is no doubt that these restrictions have served to somewhat curtail the fraudulent prescription problem.

Kinds of Forged Prescription Orders

Pharmacists should be aware of the various kinds of forged prescription orders which may be presented for dispensing:

The Forged Physician's Rx Order

(a) Legitimate prescription pads are stolen from physicians' offices, and prescription orders are written for fictitious patients.
(b) Some patients, in an effort to obtain additional amounts of legitimately prescribed drugs, alter the physician's prescription.

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*Editor's Note: The section on forged prescription orders was adapted from the article "Don't Get Trapped by Fraudulent R_x!", Delbert D. Konnor, Pharm.M.S., **Pharmacy Times**, September, 1975, Vol. 41, No. 9, pp. 46–49. Printed with permission. All rights reserved.

The Forged Hospital Rx Order

Many times, prescription pads are stolen from hospitals, and the forger uses names and addresses of fictitious patients.

Phoned-In Fraudulent Rx Orders

Some forgers prefer to telephone the prescription order to the pharmacy, and then send an accomplice to obtain the drug.

The Bogus Physician's Rx Order

Using completely false data, some forgers may have prescription pads printed to appear genuine, and then attempt to have the prescription orders dispensed.

The practiced forger of prescription orders is usually very adept at the job. The forger knows what information is needed on the prescription order to make it appear authentic. When a prescription order looks *too* good, the dispensing pharmacist should be alerted to a possible forged prescription. Consequently, it is important that the pharmacist be familiar with the prescriber's signature and method of writing prescription orders.

Proper Controls

The more difficult the pharmacist makes it for the forger to alter, forge, and pass a fraudulent prescription order, the less likely the pharmacist is to experience a forged prescription problem. This can best be accomplished by following common sense, sound professional practice, and proper dispensing procedures and controls.

Loose or routine dispensing procedures, without control and professional caution, are an invitation to the forger to make your business—*his*. By increasing the forger's risk of detection and apprehension, you will make the forger look elsewhere.

The pharmacist must be alert for forged or altered prescription orders or "prescriptions" written by (1) non-existent prescribers or for (2) non-existent patients. A prescription order for a controlled substance must be issued for a legitimate medical purpose by an individual practitioner, acting in the usual course of sound professional practice. The law holds the pharmacist responsible for knowingly dispensing a prescription issued *not* in the usual course of professional treatment. The DEA also expects that pharmacists will make a reasonable effort to determine the identity of the prescriber—if the prescriber is not known to the dispensing pharmacist.

MDs' Signature Reference File

Some pharmacists maintain a reference file of physicians' signatures. A list of physicians' addresses, telephone numbers, and DEA registration numbers also is a helpful aid and a time-saving idea. Similarly, the use of a patient profile card or any similar pharmaceutical record system facilitates patient identification. Although the maintenance of a patient drug profile card is somewhat time-consuming, it does enable the pharmacist to better perform sound professional duties. Certainly, a passer of forged prescription orders would not entertain having a patient history taken while waiting for the medication to be dispensed.

Anytime you are in doubt, require proper identification. Although the procedure isn't foolproof (identification papers can also be forged), it does increase the forger's risk potential.

If you believe that you have a forged, altered, or bogus prescription order—don't dispense it. If you have a question, call your local police.

8 Ways To Detect Fraudulent Prescription Orders

- Know the prescriber.
- Know the prescriber's signature.
- Know the prescriber's DEA registration number.
- Know the patient.
- Follow good professional practice and dispensing procedures; compromises or shortcuts may lead to errors in judgment.
- Check the date on the prescription order. Has it been presented to you in a reasonable length of time since the prescriber wrote it?
- When there is a question about any aspect of the prescription order, telephone the prescriber for verification or clarification.
- Should there be a discrepancy, the patient must have a plausible reason before the prescription medication is dispensed.

7 Characteristics of Forged Prescription Orders

- The prescription order looks too good. The prescriber's handwritting too legible;
- Quantities, directions, or dosages that differ from usual medical usage;
- Prescription orders written on hospital blanks (if you don't know the prescriber, check with the hospital to verify both the prescriber and the patient);
- Prescription orders which do not comply with the acceptable standard abbreviations or appear to be textbook presentations;
- Photocopied prescription blanks;
- Directions written in full—with no abbreviations;
- Use of different-color inks or written in different handwritings.

7 Suggestions to Prescribers

Listed below are 7 recommendations which you can pass on to *physicians* about the care and security of prescription pads. These will help reduce the number of forged prescription orders:

1) Treat prescription pads like a personal checkbook.
2) Maintain adequate security for prescription pads.
3) Stock only a minimum number of prescription pads.
4) Keep prescription pads in your possession when you are actively using them.
5) Do not leave prescription pads "unattended." When not in use, place them in a locked desk or cabinet.
6) Store surplus prescription pads in a locked drawer or a safe, appropriate area.
7) Report any prescription pad theft to local pharmacies as well as to the State Board of Pharmacy.

DEA Domestic Field Offices*

Location	Jurisdiction
Atlanta Division Richard B. Russell, FB 75 Spring Street, S.W., Rm. 740 Atlanta, Georgia 30303 (404) 331-4401	Georgia North Carolina South Carolina
Boston Division G-64 JFK Federal Building Boston, Massachusetts 02203 (617) 223-4730	Maine Massachusetts New Hampshire Rhode Island Vermont
Buffalo Resident Office The Guaranty Building 28 Church Street Buffalo, New York 14202 (716) 846-4421	Northwest New York
Chicago Division 219 South Dearborn Street Suite 500 Dirksen Federal Building Chicago, Illinois 60604 (312) 353-5839	Minnesota North Dakota Northern Illinois Wisconsin
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Detroit Division 231 W. Lafayette Room 357 Detroit, Michigan 48226 (313) 226-7290	Michigan

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Hartford Resident Office 450 Main Street Room 628-E Hartford, Connecticut 06103 (203) 244-3230	Connecticut
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Indianapolis Resident Office 575 N. Pennsylvania Room 290 Indianapolis, Indiana 46204 (317) 269-7977	Indiana
Kansas City Resident Office 812 North Seventh Street Room 206 Kansas City, Kansas 66101 (913) 236-3974	Kansas Nebraska South Dakota Western Missouri
Long Island District Office 1-Huntington Quadrangle Suite 1C-02 Melville, New York 11747 (516) 420-4500	Long Island
Los Angeles Division 350 South Figueroa Street Suite 800 Los Angeles, California 90071 (213) 688-4016	Hawaii Southern California South Nevada
Louisville Resident Office 1006 Federal Building 600 Federal Place Louisville, Kentucky 40402 (502) 582-5908	Kentucky

Location	Jurisdiction
Miami Division 8400 N.W. 53rd Street Miami, Florida 33166 (305) 591-4980	Florida
Minneapolis Resident Office 402 Federal Building 110 S. 4th. Street Minneapolis, Minnesota 55401 (612) 349-3860	Minnesota
Nashville Resident Office Estes Kefauver Building, A929 F.B.—USCM 801 Broadway Nashville, Tennessee 37203 (615) 251-5988	Tennessee
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Newark Division Federal Office Building 970 Broad Street Newark, New Jersey 07101 (201) 645-5940	New Jersey
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Philadelphia Division William J. Green Federal Building 600 Arch Street Room 10224 Philadelphia, Pennsylvania 19106 (215) 597-9540	Delaware Eastern Pennsylvania
Phoenix Division 1980 Valley Bank Center 201 N. Central Phoenix, Arizona 85073 (602) 261-4866	Arizona

Location	Jurisdiction
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San Diego Division 402 W. 35th. Street National City, California 92050 (619) 293-5654	Central California
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San Juan District Office Housing Investment Building Suite 514 416 Ponce de Leon Avenue Hato Rey, Puerto Rico 00918 (809) 754-6450	Puerto Rico
Seattle Division 220 W. Mercer Suite 301 Seattle, Washington 98119 (206) 442-5990	Alaska Idaho Montana Oregon Washington
St. Louis Division Chromalloy Plaza, Suite 200 120 South Central Avenue (314) 425-3264	Eastern Missouri Iowa Southern Illinois
Tampa Resident Office Suite 400 700 Twiggs Street Tampa, Florida 33602 (813) 228 – 2176	Northern Florida
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